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| 09/929,243      | 08/13/2001  | Gust H. Bardy        | 003.0220.01         | 8992             |

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EXAMINER

OROPEZA, FRANCES P

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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3762

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/929,243

Applicant(s)

BARDY, GUST H.

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2001 and 15 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1,5,4,5,6,7 6) ☐ Other:

## DETAILED ACTION

### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 20-24 are rejected under the judicially created doctrine of double patenting over claims 1, 2, 4, 6 and 7 of U. S. Patent No. 6277072 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Although the conflicting claims are not identical, they are not patentably distinct from each other because the application's claims are broader and are met by the narrower patented claims. The modules are read as servers.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

3. Claims 25-30 are rejected under the judicially created doctrine of double patenting over claims 12, 13, 15, 17, 18, 23, 24, and 26-28 of U. S. Patent No. 6277072 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Although the conflicting claims are not identical, they are not patentably distinct from each other because the application's claims are broader and are not by the narrower patented claims. The modules are read as servers.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 6, 10, 13, 15, 22, 23, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3 and claim 4, it is unclear if "a feedback module" of claim 3 is the same element as "a feedback module" of claim 4. Clarification is needed.

The Examiner is unable to find in the specification the terms "reference feedback" and "updated feedback" associated with claims 4, 13, 22 and 27. For this Office Action, the

Examiner reads "reference feedback" to be "reference measures" and "updated feedback" to be "updated measures" based on the instant specification, page 17 beginning at line 20.

Confirmation of this understanding is required. In addition, the terms in the claims are to follow the nomenclature of the specification, hence it appears a correction of terms is needed.

In claim 4 (lines 3-4), claim 6 (line 4), claim 13 (line 3) and claim 15 (line 4), "the patient care record" lacks antecedent basis.

In claim 4 and claim 6, it is unclear if "a database module" of claim 4 is the same element as "a database module" of claim 6. Clarification is needed.

It is unclear if "a patient status indicator" of claim 10 (lines 9-10), claim 13 (line 8) and claim 15 (line 9) is the same indicator or separate indicators. Clarification is needed.

Claim 23 (line 5) and claim 28 (line 5) are unclear because it appears "a patient care record" should be --the patient care record--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 1-5 and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Selker et al. (US 5724983).

As to claims 1-3 and 10-12, one or more clinical features (read as physiological measures) are monitored periodically to compute a change-of-condition measure (read as a patient status indicator). If the change-of-condition measure is above a threshold, an alarm notification (automated feedback) is generated (col. 1 @ 61 – col. 2 @ 11; col. 3 @ 55 – col. 4 @ 65).

As to claim 4 and 13, S-T segment depressions and elevations (the reference feedback) and the ECG wave (the physiological measure) are monitored by the system (col. 2 @ 54-60).

As to claims 5 and 14, the reference baseline is periodically revised (col. 5 @ 8-18).

7. Claims 1-5 and 10-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson (US 6155267).

As to claims 1, 2, 10, and 11, chronic data from at least one sensor is monitored by the monitoring software (56) to establish a baseline. Periodically, chronic data is monitored to detect a change in state from the baseline (col. 2 @ 53-64). Substantial nonconforming measures are identified and indicted by a communication signal or an alarm (read as a patient status indicator) (col. 10 @ 2-13).

As to claims 3 and 12, the alarm is read as feedback (col. 10 @ 11-20).

As to claims 4 and 13, the oxygen sensor data (the reference feedback) and the pressure sensor (the physiological measure) are monitored by the system (col. 10 @ 28-41).

As to claims 5 and 14, the reference baseline is periodically revised (col. 8 @ 12-16).

*Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint Inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. The Applicant is advised of the obligation under 37 CFR 1.56 to point out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 6, 15 and 20-29 rejected under 35 U.S.C. 103(a) as being unpatentable over Selker et al. (US 5724983) in view of Brown (US 6168563). As discussed in paragraph 6 of this action, Selker et al. disclose the claimed invention except for: 1) storing all monitored data, and 2) monitoring and recording quality of life measurements.

As to storing data, Brown teaches health monitoring using memory for the purpose of storing all collected data. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used memory to store all the data in the Selker et al. system in order to enable the health care provider to review the data in its entirety, record the data for later use, and/ or use the data to perform various analyses (col. 9 @ 2-19; col. 9@ 61 – col. 10 @ 2).

As to the quality of life measurements, Brown teaches health monitoring using quality of life measurements for the purpose adding the subjective patient perspective information to the simultaneously measured physiological parameters so the caregiver has a more comprehensive understanding of the patient's condition. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used quality of life measurements in the Selker et al. system to enable the health care provider to more optimally monitor and manage the health care condition of the patient (Abstract; figures 13 and 16; col. 6 @ 4-7; col. 9 @ 20-60).

10. Claims 7-9 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selker et al. (US 5724983) in view of Levine (US 4852570). As discussed in paragraph 6 of this action, Selker et al. disclose the claimed invention except for monitoring a prescribed exercise session and identifying abnormal activity or exercise.

Levine teaches medical physical analysis using a prescribed exercise session for the purpose of identifying abnormal activity or exercise indicative of illness or malfunction. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used monitoring of prescribed exercise sessions to identify abnormal activity or exercise in the Selker et al. system in order to provide an alternate measure that identifies long-term changes or trends in a patient's health (Abstract; col. 10 @ 59 – col. 12 @ 38).

11. Claims 19 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Selker et al. (US 5724983) in view of Brown (US 6168563) and further in view of Levine (US 4852570) and further in view of Selker et al. (US 6067466). As discussed in paragraphs 6, 9 and 10 of this action, modified Selker et al. (US 5724983) disclose the claimed invention except



for providing a computer-readable storage medium holding code for performing the methods of this invention.

Selker et al. (US 6067466) teach computer program transfer using a computer readable medium for the purpose of entering an analysis/ diagnostic program in a processing module or computer. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a computer readable medium in the Selker et al. (US 5724983) system in order to provide a typical means of entering the analysis/ diagnostic program into a computer so the program is efficiently and effectively read/ loaded into the processor module/ computer (col. 3 @ 27-37 and 54-57).

#### *Abstract*

14. The abstract of the disclosure is objected to because of the phrase "is described" in line 2.

The Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc. Correction is required. See MPEP § 608.01(b).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

*FPO*  
*3/6/03*

*Angela D. Sykes*

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